

Appl. No. 10/820,824  
Amendment dated: October 30, 2008  
Reply to OA of: July 9, 2008

### **REMARKS**

Applicants have amended the claims to more particularly define the invention taking into consideration the outstanding Official Action. Applicants have amended claims 12 and 15 and have canceled claims 1-11 and 17-22 from the present application without prejudice or disclaimer. Applicants submit that all of the claims now present in the application are fully supported by the specification as originally filed and no new matter is introduced.

Applicants note that Applicants election without traverse of claims 12-16 (Group II) on 4/7/08 is acknowledged. Claims 1-11 and 17-22 are withdrawn from further consideration as being drawn to a nonelected invention. Applicants have canceled claims 1-11 and 17-22 from the present application. Applicants retain their right to file a divisional application at a later time.

Applicants further note that receipt is acknowledged of papers (Taiwan 92123622, filed 8/27/03) submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

The rejection of claims 12-16 under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention has been carefully considered but is most respectfully traversed in view of the amendments to the claims 12 and 15. Claim 12 has been amended to provide proper antecedent basis for transducer and claim 15 to correct an obvious error. These amendments are fully supported by the specification as would be fully appreciated by one of ordinary skill in the art to which the invention pertains. Accordingly, it is most respectfully requested that this rejection be withdrawn.

Applicants most respectfully submit that all of the claims now present in the application are in full compliance with 35 USC 112 and clearly patentable over the references of record.

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The rejection of claims 12-16 under 35 USC 102(b) as being anticipated by Lewandrowski et al. has been carefully considered but is most respectfully traversed in view of the amendments to the claims and the following comments.

Applicants wish to direct the Examiner's attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed.Cir. 1990).

In this regard, Lewandrowski et al. (US Pub. No. 20020137082) relates to a method for diagnosing osteoporosis by measuring the concentration of the predominant chaperone molecule, then comparing the concentration obtained with a frequency table containing correlations between other factors such as age, gender, and the presence of chaperone molecule to evaluate the probability of osteoporosis (referring to paragraphs [0159], [0160]). It must be emphasized that Lewandrowski et al does NOT measure bone mineral density numerically, instead, the concentration of the chaperone molecule is measured, and this data is then simply **categorized to either having or not having osteoporosis** using a frequency table. In other words, Lewandrowski et al simply determines whether a sample is osteoporotic, while the present invention aims at detecting the bone mineral density level, for which the purpose, the method, as well as the outcome are significantly different.

Following the fundamental difference between Lewandrowski et al and the present invention as mentioned above, it is apparent that Lewandrowski et al has not

disclosed any DEVICE for measuring bone density but merely mentioned CONVENTIONAL METHODS in the definitions section. The characteristics in Lewandrowski et al. being referred to as corresponding to elements in the biosensor of the present invention are **the combination of elements in many different methods** with functions and purposes departing from the spirit and scope of the present invention, the detailed analysis is as follows:

- a. Lewandrowski et al. has disclosed the use of a laser beam in paragraph [0024] as mentioned by the examiner, which was referred to as corresponding to the “stimulating source” of the present invention. However, the laser beam in Lewandrowski et al. is used in **Protein 200 Assay** for detecting the fluorescence of the labeled protein molecule. Comparing to the present invention, there is NO incorporation of the Protein 200 Assay technique, and the stimulating source is used to INDUCE signals when contacting the transducer surface, not to DETECT fluorescence emitted. Therefore, the stimulating source of the present invention should not be considered as being disclosed by Lewandrowski et al.
- b. Lewandrowski et al. has disclosed the use of heat shock proteins (HSPs), osteocalcin, and plasma tartrate-resistant acid phosphatase (TRAP) as biomarkers for bone turnover (referring to paragraphs [0010], [0036] and [0104]). However, there is no disclosure corresponding to the “transducer having at least one cantilever beam deposited thereon, wherein the surface of said cantilever beam is immobilized with antibodies against TRAP 5a, TRAP5b, or total TRAP”. Firstly, Lewandrowski et al. did not mention the use of a transducer with immobilized antibody as part of the method for detecting biomarker concentration but merely mentioned the use of **Protein 200 Assay**, a conventional protein assay method, in which the biomarker concentration is determined by the **amount of**

**fluorescence** detected. On the other hand, the surface of the cantilever beam is immobilized with TRAP antibodies, for which the biomarker concentration is determined by the added weight upon binding, causing **shift in resonance frequency** (referring to page 15, lines 7-8). Therefore, the transducer of the present invention should not be considered as being disclosed by Lewandrowski et al.

- c. Lewandrowski et al. has disclosed a step of measuring the absorption of the purified biomarker (paragraph [0080]), as well as the method for categorizing the obtained data into osteoporosis or non-osteoporosis (paragraphs [0082] and [0159]). Firstly, as mentioned above, these disclosures are merely methods, not devices, therefore the devices "signal detecting unit for detecting signal changes from said transducer" and the "signal processing unit for retrieving and analyzing said signals" in the present invention were not disclosed in Lewandrowski et al. Secondly, the function of the signal detecting unit in the present invention has been specified as "for detecting signal changes from said transducer". Comparing to Lewandrowski et al., the "signal detection" is merely measuring a SINGLE VALUE of the absorption of a purified biomarker, while the signal detecting unit of the present invention is detecting the CHANGE OF SIGNAL. Therefore, the signal detecting unit and the signal processing unit of the present invention should not be considered as being disclosed by Lewandrowski et al.

Finally, Lewandrowski has not disclosed a device with elements corresponding exactly to the biosensor for measuring bone mineral density in the present invention, since relevant disclosures in Lewandrowski et al. cited by the Examiner were merely conventional analytical methods, not devices. Therefore, the present invention indeed has novelty over Lewandrowski et al.

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The method used in Lewandrowski et al. is significantly different from the present invention, with very different purposes, functions, and outcomes. Therefore, the present invention should not be considered as being disclosed by Lewandrowski et al., and is therefore novel over Lewandrowski et al. Accordingly, it is most respectfully requested that this rejection be withdrawn.

In view of the above comments and further amendments to the claims, favorable reconsideration and allowance of all the claims now present in the application are most respectfully requested.

Respectfully submitted,  
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